EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

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IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2875
	:	CIVIL NO. 19-2875 (RBK/JS)
THIS DOCUMENT APPLIES TO ALL CASES	:	HON. ROBERT B. KUGLER

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

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SEPTEMBER 29, 2021

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Videotaped remote deposition of LEWIS A. CHODOSH, M.D., Ph.D., taken pursuant to notice, was held at GREENBERG TRAURIG, LLP, 1717 Arch Street, Suite 400, Philadelphia, Pennsylvania, via Zoom Videoconference, beginning at 9:24 A.M. (EST), on the above date, before Margaret M. Reihl, RPR, CRR, CCR-NJ.

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when you have a nongenotoxic chemical versus a genotoxic chemical?

A. So you're talking about regulatory issues for calculating safe doses, which is not my domain, other than to say for genotoxic carcinogens the FDA guidance on their -- with a safety mandate is to use linear low dose extrapolation, which assumes effectively that one molecule of an agent will increase the risk of cancer, whereas, to my recollection, nongenotoxic carcinogens are considered to have thresholds and, of course, the suitability from a biological perspective of the assumption by FDA, essentially that linear low dose extrapolation is biologically accurate at the exceedingly low doses that are at issue in this litigation, I think most scientists, cancer biologists would say that that is -- those are overly conservative assumptions which are appropriate for a safety mandate of the FDA, but from the biological perspective of causation, they do not make biological sense.

Q. How many molecules of NDMA are in 1 nanogram?

A. I believe it's going to be

somewhere in the vicinity of 7 trillion.

Q. In 1 nanogram of NDMA?

A. That's correct.

Q. So in --

A. And I'm doing this at whatever time this is at night, sitting here in this deposition. I believe it's somewhere in the range of 7 trillion molecules for a nanogram, maybe a little bit more than that.

Q. So in 96 nanograms that would be 96 times 7 trillion molecules, correct?

A. Going to be 700, 750 trillion molecules, which if you needed a common sense demonstration that the notion that one molecule is biologically meaningful when 700 trillion molecules is considered to be safe by the FDA with a safety mandate QED, clearly, that one molecule is not biologically meaningful, just one of the many reasons why one molecule cannot reasonably be considered to increase risk of cancer.

Q. The highest level of NDMA that's noted by the FDA in their laboratory analysis of valsartan products is 20.19 micrograms, correct?

A. That's correct.

Q. How many molecules of NDMA would be in 20.19 micrograms?

A. I can't sit here and do the math but what I can tell you is that whatever that number is, the number of molecules that our body produces every day is a thousand times higher than that.

Q. That's not the question I asked.

A. That's the answer that I can give you without a calculator in front of me.

MS. BOGDAN: All right. Let's take a break. I am done for tonight.

THE VIDEOGRAPHER: Standby. 7:26 we are off the video record.

(Witness excused.)

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C E R T I F I C A T I O N

I, MARGARET M. REIHL, a Registered Professional Reporter, Certified Realtime Reporter, Certified Court Reporter, Certified LiveNote Reporter, do hereby certify that the foregoing is a true and accurate transcript of the testimony as taken stenographically, by and before me, remotely, via Zoom, to the best of my ability, and on the date hereinbefore set forth.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

Margaret M. Reihl, RPR, CRR, CLR
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of NDMA would cause a detectable increase in risk.

In contrast to that what we know from biology is that there are DNA repair systems that are designed to repair just this type of DNA damage. There's even a specific system that has evolved in mammals to directly repair, completely repair any DNA damage that would be caused by NDMA.

And the point is is that at these very low exogenous exposure levels they're so much lower than our endogenous levels that the expectation would be that any DNA damage would be repaired. And let me simplify it to say that if our bodies are -- day in and day out are used to repairing damage from endogenously produced NDMA of a thousand molecules a day, what even these largest theoretical maximum doses are for valsartan, basically, would represent one more molecule. So this is well within the physiological range that we have evolved to repair DNA damage of exactly this type.

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BY MR. INSOGNA:

Q. And just so we have a very simple explanation of this for the record, when you refer to endogenously produced NDMA, what does that mean?

A. What I mean is that if we look at the metabolism of our cells and tissues, in the absence of any exposures to NDMA in the outside world, our bodies produce chemicals like NDMA and NDEA. We know that they are present even in individuals where we do not think that they've been exposed. You see them in animals, you see them in human beings. So that's what I mean by endogenously produced.

Q. And so if the assumption from linear low dose extrapolation that there is no threshold, that there is no DNA repair mechanism, if that assumption were accurate what would the assumption be?

A. If there was no DNA repair --

MS. BOGDAN: Objection to form.

THE WITNESS: If there was no DNA repair, given the very high levels or the levels of endogenous NDMA that our bodies are producing all the time, most of us, if

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not all of us, would have liver cancer.

And I guess the best way to explain the threshold is to say if I damage a nucleotide in DNA and then I repair it, it has no effect, that cannot lead to a mutation. So as long as the DNA damage occurs within a range that can be repaired, there will be no damage. So it will not be until one rises above that threshold of DNA repair where you would begin to have a significant potential of mutations and because our bodies evolve to deal with the levels that we have, our DNA repair systems evolved to accommodate the endogenous levels of NDMA and other nitrosamines that we all produce in our bodies every day.

BY MR. INSOGNA:

Q. Okay. You can put aside that document.

Counsel asked you some questions today about the key characteristics of cancer and I believe you testified that you considered those characteristics in forming your opinions in this case; is that right?

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A. That's correct.

Q. Okay. How, if at all, do those characteristics fit with the opinions that you've offered?

A. Well, those particular key characteristics are things that I consider but they are descriptions of just some of the properties and information that one would consider in making an assessment of carcinogenicity.

I mean, for instance, that list doesn't even have studies of carcinogenicity on them and there are multiple, quote, key characteristics that were listed in that list for which my opinion is NDMA and NDEA don't fulfill those, but this is just sort of one slice of the pie of things that one would consider in reaching an opinion or a conclusion about carcinogenicity of a compound.

Q. Shifting gears a little bit, counsel showed you a number of dietary studies today and I believe you agreed that some of them on their face showed statistically significant associations in some categories.

First, did you consider the dietary studies in forming your opinions in this case?